



U.S. PUBLIC HEALTH SERVICE
Pharmacist Professional Advisory Committee
Department of Health and Human Services

Minutes of Meeting
03 January 2013
FDA White Oak Conference Room 1419
1400-1530

Members Present

RADM Scott Giberson (CPO), DCCPR-Rockville,
MD CDR Michael Crockett (Chair), BOP-Pollock,
LA
LCDR Marisol Martinez (Chair-Elect), DoD-FT
Sam Houston, TX
CAPT Aaron Sigler, FDA-Rockville, MD
CDR Kavita Dada, FDA-Silver Spring, MD
CDR Janelle Derbis, FDA-Chicago, IL
CDR Jefferson Fredy, IHS-Crownpoint, NM
CDR Dean Goroski (Alt.),
CDR Jinhee Lee, SAMHSA-Rockville, MD
CDR Aaron Middlekauff, DHS-Washington DC
CDR Mark Miller, FDA-Silver Spring, MD (Alt.)
CDR Juliette Touré, FDA-Silver Spring, MD
CDR MaryJo Zunic, IHS-Albuquerque, NM

LCDR Stephanie Arnold (Alt.), IHS-Salina, OK
LCDR Troy Bernardo, BOP-Butner, NC
LCDR Tiffanie Dunlevy, BOP-FCI Marianna, FL
LCDR Brittany Keener, IHS-Anchorage, AK
LCDR Kara King, IHS-Anchorage, AK
LCDR Khang Ngo, IHS-Taholah, WA
CDR Timothy Bowman (Assoc.), DHS-Houston,
TX
CDR Carmen Kelly (Assoc.), AHRQ-Rockville,
MD
LCDR Liatte Krueger (Assoc.), FDA-Parsippany,
NJ CDR Peter Diak (Ex-Officio), FDA-Silver
Spring, MD
LCDR Rodney Waite, BOP-Milan, MI

*indicates PharmPAC alternate

Excused members: CDR Timothy Murray, IHS-Claremore, OK*; LCDR Selena Ready, FDA-Silver
Spring, MD*; LCDR Jodi Tricinella, IHS-Claremore, OK*; CAPT Greg Dill (Assoc.), CMS-Chicago, IL;
CDR Fortin Georges (Assoc.), NIH-Bethesda, MD; CDR Lori Hall (Assoc.), CDC-Atlanta, GA; LCDR
Kenda Jefferson (Assoc.), DHS-Washington DC

*Voting Member's alternate was present

Call to Order: CDR Michael Crockett (mcrockett@bop.gov)

Meeting began at 1403EST.

CPO Report & Open Forum → RADM Scott Giberson

- Happy New Year
- CPO Update to be distributed after this meeting.
- 2012 was good year for the Pharmacy Category.
- RADM Giberson's last month as CPO will be March 2014.
- It is the responsibility of officers to read the CPO Updates to be informed about what is occurring at Headquarters.
- Deployments currently to Hurricane Sandy, Newtown CT, CNMI (Marianas Islands). Thanks to officers deployed, officers who picked up the workload, the supervisors, and agencies allowing this.
- Will be consequences if only maintain Basic Ready during promotion years as per policy.
- Officers may be seeing vacancy announcements for HQ positions and it seem like we are adding staff, but HQ is actually losing positions than gaining, but should stabilize this year at about 50 staff.
- Congratulations to CDR Crockett at being selected as the "Chair of Chairs" for the overall PAC group.
- Will likely open up for New PHS Officer applications again in June 2013 and will be highly selective and controlled.
- COSTEP will continue for pharmacy. Will only be for pharmacy, EHO, and engineers.
- APFT initiative will hopefully inspire category to conduct the APFT.
- COA/COF: be prepared to pay your own way. May get funding but do not wait for it.
- Recent articles pertaining the USPHS Pharmacy
 - Article published in the APhA Pharmacy Today December Issue.
 - U.S. Medicine 2013 Outlook should be published in January 2013.
- Q: CDR Crockett how will MAB backlog be handled with respect to submission deadlines.
A: Wait for fax confirmation printout as a receipt for date/time of submission. Then, wait at least 1 month after submission to check by sending an e-mail with a scanned copy of the fax confirmation printout attached. This allows us to assess the nature/extent of backlog and is the method being used currently.
- Q: LCDR Zee: What are the JrCOSTEP/SrCOSTEP program acceptance numbers? How many slots are available in each?
A: The number of slots is determined by the funding in the agencies, with the bulk coming from IHS.

Readiness Section → CDR Janelle Derbis (Janelle.derbis@fda.hhs.gov) / CDR Juliette Touré (Juliette.toure@fda.hhs.gov) / LCDR Troy Bernardo (tbernardo@bop.gov)

- CDR Touré: Reminder of the December 21st announcement from OFRD asking for a pharmacist to volunteer for the CNMI (Marianas) deployments. This candidate would preferably have IHS Inpatient Hospital experience.
- APFT initiative: choose this year to improve fitness and complete the APFT. More to come!

Communication Section → CDR MaryJo Zunic (MaryJo.Zunic@ihs.gov) / LCDR Khang Ngo (Khang.Ngo.USPHS@hotmail.com) / LCDR Jodi Tricinella (jodi.tricinella@ihs.gov)

- Pharmacy Perspectives Newsletter: there will be upcoming solicitations for articles with guidelines for submissions.
- Publications Webinar: Sent a survey soliciting feedback for future webinars on 12-21-2012, will re-send soon.
- Q: CDR Crockett asked if the Pharmacy Newsletter will be sent out via the PharmPAC listserv?
A: Yes.

Career Development Section → CAPT Aaron Sigler (Aaron.Sigler@fda.hhs.gov) / CDR Jefferson Fredy (jefferson.fredy@ihs.gov) / LCDR Tiffanie Dunlevy (tmyers@bop.gov)

- CCPMN: mentoring program still going well. If want to be a mentor or mentee, then contact CDR Ruby Wu (chi-ann.wu@fda.hhs.gov), CCPMN Coordinator.
- Q: What are the qualifications of being a mentor?
A: Listed on website: http://www.usphs.gov/corpslinks/pharmacy/sc_career_mentoring.aspx
 - O-4 and above.
 - Should be at least 2 ranks higher than mentee, when possible.
 - Should not be in mentee's direct supervisory chain of command.

Administration Section → CDR Kavita Dada (kavita.dada@fda.hhs.gov) / CDR Jinhee Lee (Jinhee.Lee@samhsa.hhs.gov) / CDR Timothy Murray (timothy.murray@ihs.gov) /

- Pharmacy Professional Liaison Group vacancies will be announced in next few weeks via listserv.

Recruitment Section → CDR Aaron Middlekauff (Aaron.p.middlekauff@uscg.mil) / LCDR Brittany Keener (blkeener@anthc.org) / LCDR Kara King (kaking@anthc.org)

- USPHS Excellence in Pharmacy Practice Student Award deadline will be 8 March 2013. Questions, then please contact LCDR Keener at blkeener@anthc.org, usphspharmacist@gmail.com, or call 907-729-2144
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Chair Report → CDR Michael Crockett (mcrockett@bop.gov)

- JOAG Awards: Nominations will now be accepted until the deadline of 28 January 2013 for the 3 awards presented at the COA Conference (in Glendale, AZ). This year's awards will be:
 - 1) JOAG Excellence Award
 - 2) Junior Officer of the Year Award
 - 3) VADM Richard H. Carmona Inspiration Award
 - Nomination Packet Can Be Found Here:
http://www.usphs.gov/corpslinks/JOAG/documents/JOAG_Call_for_Award_Nominations.pdf
 - JOAG Awards Page can be found here:
<http://www.usphs.gov/corpslinks/JOAG/awards.aspx>
 - OBC 60 to begin 06 January 2013 through 18 January 2013. Feel free to come to the open house on 10 January 2013 or the graduation on 18 January 2013.
 - APhA: Federal Pharmacy Forum will be 01 March 2013. We are still seeking one APhA House of Delegates alternate and one APhA-PharmPAC liaison.
 - COTA (Mid-Level OBC): postponed, may possibly start summer 2013. Your PharmPAC will announce when COTA opens up to a broader audience.
 - New Year's Resolution: Embrace the Core Values this year.
 - **Leadership:** Provides vision and purpose in public health through inspiration, dedication, and loyalty.
 - **Service:** Demonstrates a commitment to public health through compassionate actions and stewardship of time, resources, and talents.
 - **Integrity:** Exemplifies uncompromising ethical conduct and maintains the highest standards of responsibility and accountability.
 - **Excellence:** Exhibits superior performance and continues improvement in knowledge and expertise.
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Chair-Elect Report → LCDR Marisol Martinez (Marisol.Martinez@AMEDD.ARMY.mil)

- Remain Basic Ready
 - Assist Communications Section in contributing to Pharmacy Perspectives Newsletter
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Old/New Business → CDR Michael Crockett (mcrockett@bop.gov)

- LCDR Ngo's (Khang.Ngo.USPHS@hotmail.com) Symposium update: No new items, but a few reminders:
 - There is no new information to report since our December meeting. However, I do have a few reminders. Registration for the Symposium is now open. Visit the Symposium website for different types of registration and rates. In addition to the full conference registration, there are options for one-day, speaker, student/spouse/guest, as well as other events such as the pre- and post-conference sessions and the Anchor

- & Caduceus Dinner. If you are a junior officer of rank O-3 or below, or civil servant GS 10/11 or below, be sure to apply for the scholarships.
- If you are making reservations for accommodations at the Renaissance Hotel, be sure to use group code USPUSPA for the government rate of \$128.
 - We are currently working with LCDR John Watts, one of the music directors of the PHS Music Ensembles, to premiere the Pharmacy March on Category Day. He is looking for officers interested in collaborating with him to write lyrics for the March. If you are interested, please contact LCDR Watts directly at jwatts@cdc.gov.

The meeting was adjourned @1442 .

Next Meeting Date: 07 February 2013, from 1400 to 1530 EST, White Oak Conference Room Bldg 22, Room 1419; Agenda and call-in information will be distributed prior to the meeting.

Useful Links and Contact Info:

- ◆ Emails: PharmPAC@list.nih.gov
PHS-Pharmacists@list.nih.gov
PHS-RX-JOBS@list.nih.gov
PHS-Rx-Students@list.nih.gov
- ◆ Listservs: PHS Pharmacists <https://list.nih.gov/archives/phs-pharmacists.html>
PHS Rx Students <https://list.nih.gov/archives/phs-rx-students.html>
OFRD <https://list.nih.gov/cgi-bin/wa.exe?A0=ofrd>
RPh Job Vacancies <https://list.nih.gov/archives/phs-rx-jobs.html>
CCMIS <http://ccmis.usphs.gov/ccmis>
CC Vacancies <https://list.nih.gov/archives/ccvacancies-l.html>
PHS Immunizing Pharmacists <https://list.nih.gov/archives/phs-immunizing-pharm.html>
JOAG <https://list.nih.gov/archives/joag.html>
- ◆ Websites: PharmPAC <http://www.usphs.gov/corpslinks/pharmacy>
CCMIS <http://dcp.psc.gov>
USPHS <http://www.usphs.gov>
OFRD <http://oep.osophs.dhhs.gov/ccrf>
Facebook <http://www.facebook.com/USPHSPharmacists>
JOAG <http://www.usphs.gov/corpslinks/joag/>

--Respectfully Submitted,

____Rodney C. Waite_____/ _ 07 February 2013____
LCDR Rodney Waite II, Executive Secretary Date

CDR Michael Crockett, Chair

Date

RADM Scott Giberson, CPO

Date

Attachments:

- 1. BOP Liaison Report**
- 2. CDC Liaison Report**
- 3. CMS Liaison Report**
- 4. COA Liaison Report**
- 5. FDA Liaison Report**
- 6. IHS Liaison Report – Not included this month**
- 7. JOAG Liaison Report – Not included this month**
- 8. NIH Liaison Report – Not included this month**
- 9. Recruitment Report – Not included this month**
- 10. CPO Update**

BOP Liaison Report

- CDR Kathleen Dotson, Chief Pharmacist, United States Medical Center for Federal Inmates, Springfield, MO, is currently deployed to Saipan.
- A comprehensive inventory of all BOP Pharmacy Program workgroups and activities is being created. This detailed listing will help document how the BOP Pharmacy Program has evolved, provide points of contact for specific areas, and assist with formalizing the corporate knowledge of the program.
- RADM Chris Bina is scheduled to provide the keynote address at the Iowa Pharmacist's Association Meeting and Expo, as well as provide a presentation to Drake University Pharmacy Students in February.
- BOP Clinical Pharmacy continues to grow! Currently over 80 active clinical pharmacy protocols via a Collaborative Practice Agreement across the agency with more on the way.
- New institution in Aliceville, AL has been activated and just started receiving inmates.

CMS Liaison Report

January 2013

CMS Agency Report to PharmPAC

Submitted by CDR Matthew D. Febbo

People with Medicare save \$5 billion on prescription drugs because of health care law *Additional value possible with plan options during Open Enrollment:*

As the final week of Medicare Open Enrollment approaches, Health and Human Services Secretary Kathleen Sebelius announced today that savings on prescription drugs made possible by the Affordable Care Act reached \$5.1 billion. More than 5.8 million people with Medicare have benefited from the assistance the health care law provides with the Medicare prescription drug coverage gap known as the donut hole. In the first 10 months of 2012 alone, almost 2.8 million individuals have saved an average of \$677 on prescription drugs. During the same period, about 23.4 million people with original Medicare received one or more preventive services at no cost to them, with 2.5 million having received an Annual Wellness Visit.

COA Liaison Report

Commissioned Officer Association (COA) Liaison Report

Compiled by LCDR Alexis Beyer

COA is dedicated to improving and protecting the public health of the United States by addressing unmet health needs and providing support for more than 7,000 members.

Announcements:

NDAA Conferees Include All Uniformed Services in Autism Pilot

12/19/2012 - Last night, the House and Senate came together and approved a TRICARE pilot program for the treatment of autism spectrum disorders that will expand coverage of applied behavioral analysis (ABA). It will include all seven federal uniformed services. It will be accessible to active-duty and retired service members.

It happened as House and Senate conferees ironed out the differences in their respective versions of the FY 2013 National Defense Authorization Act (NDAA).

COA's top legislative priority for the last four months has been to convince the U.S. Congress not to discriminate by uniform. It seemed headed in that direction. The House would have excluded all USPHS, NOAA, and USCG personnel from the autism benefit. The Senate would have excluded USPHS, NOAA, and USCG retirees. Either would have established an unacceptable precedent in federal law by limiting or denying a TRICARE benefit based on one's branch of service.

Fortunately, House and Senate conferees scrapped both versions and started anew. The autism program is now authorized in bare-bones language in Sec. 705 of HR 4310. Its inclusiveness is made clear in the Joint Explanatory Statement, a supplementary document issued by the House Rules Committee. It says the autism program is "for all TRICARE beneficiaries covered under the basic program."

Since the discrimination issue surfaced in August, two dozen PHS parents of autistic children, including five retirees, have worked closely with COA staff to inform and educate their members of Congress. These parents and COA members shared details about their children, their deployments, and their PHS careers. Their stories proved compelling.

PHS Commissioned Corps Helps Sandy Hook Tragedy Survivors

12/18/2012 - The PHS Commissioned Corps Mental Health Team Four deployed to Sandy Hook, Connecticut on the evening of Friday, 14 December to provide counseling services to the community devastated by the school shootings there. Sixteen members of the team were on the ground in Sandy Hook by Saturday morning with fourteen more enroute.

The team's deployment is yet another example of the responsiveness, flexibility, and capability of the PHS Commissioned Corps in addressing the nation's public health needs. In recent weeks, the Corps has deployed officers to support superstorm Sandy relief efforts in New York and New Jersey, another team to provide medical administrative and clinical support to a troubled hospital in Saipan, and now another team to help the distraught citizens of Sandy Hook cope with the horror they are enduring.

At the same time Corps officers are planning and preparing to deploy in support of the presidential inauguration in January - all while continuing to execute their critical primary duty assignments in medical research at NIH; disease prevention at CDC; food and drug administration and regulation at FDA; clinical care and medical

infrastructure support for underserved populations of Native Americans and Alaska Natives in the Indian Health Service; supporting health care and critical missions in the Department of Defense; and working in dangerous and thankless environments caring for federal prisoners in the Bureau of Prisons and detainees in illegal immigrant detention centers in the Department of Homeland Security and much, much more.

The 6700 officers of the PHS Commissioned Corps will touch the lives of each and every citizen of the United States at some point, often at times of desperation and crisis. The question for each of us is, will we recognize them when they protect us from disease, help us recover from disaster, care for us when no one else will?

Senator Daniel K. Inouye, 1924-2012, Public Health Champion and Friend of the PHS Commissioned Corps

12/18/2012 - Senator Daniel K. Inouye (D-HI), the Commissioned Officers Association's 2010 Health Leader of the Year passed away due to respiratory complications on December 17th. Senator Inouye, in a career of public service spanning 80 years, was awarded the Congressional Medal of Honor for heroism during World War II, served as Hawaii's first congressional representative in 1959, and was elected to the Senate in 1962 where he served with distinction for almost nine consecutive terms. At his death Senator Inouye was president pro tempore of the Senate and third in line of succession to the presidency and was chairman of the powerful Senate Appropriations Committee.

Senator Inouye postponed plans to become a physician when he joined the Army in 1942 at the age of 17 following the attack on Pearl Harbor. The Senator was severely wounded and lost an arm in an attack on machine gun nests on a hill in Italy in 1945 - an act of heroism for which he was awarded the Medal of Honor.

The loss of his right arm derailed his plans to become a physician and he instead studied law graduating from George Washington University School of Law. He returned to Hawaii and began a career as a city and county attorney and Democratic Party activist. In his more than 50 years in Congress, Dan Inouye was recognized as a statesman of the old school who sought out bi-partisan compromise and always placed the good of his country above partisan politics. He was a champion of veteran's programs, public health, the nursing profession, and the PHS Commissioned Corps. Senator Inouye was instrumental in obtaining access to Post 9/11 GI Bill benefits for PHS Commissioned Corps officers. His support for the Corps and this association will be greatly missed. COA extends our sincere condolences to his widow, son and family, and the Senator's staff. We bid the Senator a sad Aloha.

Commissioned Corps Strike Team Composed of COA Members Deploys to Commonwealth of the Northern Mariana Islands for Health Mission

12/14/2012 - A six person team of PHS officers, all members of the Commissioned Officers Association, has arrived in Saipan for a three month hospital technical assistance mission Surgeon General Regina Benjamin announced today.

The team, led by RADM Newton Kendig (Federal Bureau of Prisons - BOP), is providing technical assistance to the Commonwealth Health Corporation hospital and direct patient care. Additional team members include CAPT Lisa Hogan, nurse manager (BOP); CDR Daniel Hesselgesser, clinical laboratory manager (Centers for Medicare and Medicaid Services - CMS); CDR Sylvie Cohen, physician/safety officer (BOP); CDR Kathleen Dotson, pharmacy manager (BOP); and LT Lane Vause, medical technologist (CMS). The team is expected to expand in coming weeks.

Kendig, in an interview with reporters on Saipan, said there will be a total of 10 to 11 medical personnel that will be assisting the CNMI, including four to five that will be arriving later. "My chain of command is with the Surgeon General's Office in Washington, and we're being deployed here as officers to work with the governor's office and the healthcare corporation. We were deployed here to provide technical assistance. We are here on the spirit of teamwork and collaboration to see what we can do to help Saipan," he said.

TRICARE Dental Benefits

12/14/2012 - Good News!! PHS active duty and their family members are eligible for TRICARE dental benefits through Metlife.

For more information, please go to: www.metlife.com/tricare
[TRICARE Dental Benefits](#)

COA Fights Discrimination in TRICARE Benefits

12/10/2012 - COA is fighting an unprecedented move to limit or deny basic TRICARE health benefits on the basis of one's branch of service. The issue is playing out in the context of a House-approved measure to enhance TRICARE coverage for autism spectrum disorders. The House would extend the more generous coverage to all active-duty and retired uniformed services personnel except those in the PHS, NOAA Corps, and U.S. Coast Guard. The Senate voted to extend the proposed coverage to "currently serving" personnel in the three smallest services. But the Senate would still leave out PHS, NOAA, and USCG retirees.

TRICARE covers 9.7 million beneficiaries. The House would exclude 22 COA members and TRICARE beneficiaries who are the parents of 23 young children with autism. The Senate would include 18 of these PHS families, but deny coverage to 4 PHS retirees who have autistic children as young as 8.

The issue is being decided right now, as House and Senate conferees reconcile their differences in the National Defense Authorization Act (NDAA) for FY 2013. Click here to read COA's letter to leaders of the Armed Services Committees in both chambers.

[Click here to read COA's letter to leaders of the Armed Services Committees in both chambers...](#)

Registration is Now Open for USPHS Symposium, Abstract Deadline Extended

12/06/2012 - Online registration for the 2013 USPHS Scientific and Training Symposium is now open. The Symposium will be held May 21-23, 2013 at the Renaissance Hotel in Glendale, Arizona. Attendees can book room reservations online. The planning committee has also announced that the Call for Abstracts for the Symposium has been extended to December 17.

The theme for this year's conference is "Public Health Prevention and Care: Bridging the Gaps."

[Register](#)

Disease Prevention Initiatives Project Grant Proposals Invited

12/03/2012 - JBS International, Inc. seeks to award evidence-based projects that enhance disease prevention initiatives and improve health outcomes by (i) increasing routine HPV vaccination coverage for adolescents and persons up to 24 years of age and (ii) increasing the proportion of adults vaccinated against seasonal influenza and other preventable illnesses. Eligible applicants are invited to submit proposals to fund activities specific to Community or Systems-level Interventions. Visit [JBS International](#) to view the full proposal and other details.

FDA Liaison Report

FDA AGENCY REPORT – January 2013

Report to the USPHS PharmPAC

Submitted by FDA Agency Liaison: LT Sadhna Khatri, MS, Pharm.D, Office of Communications, Division of Drug Information.

Here is a summary of recent product safety, product approvals and announcements to keep you informed about FDA issues. A brief summary of each issue and a web link to detailed information on the FDA website is included.

PRODUCT SAFETY:

[Serious Skin Reactions with Incivek \(telaprevir\) In Combination with Peginterferon Alfa and Ribavirin \(Incivek combination treatment\)](#) (Dec 19)

FDA received reports of serious skin reactions, some fatal, in patients taking Incivek, a hepatic C virus NS3/4A protease inhibitor for the treatment of genotype 1 chronic hepatitis C. FDA is adding a boxed warning to the Incivek drug label stating that Incivek combination treatment must be immediately stopped in patients experiencing a rash with systemic symptoms or a progressive severe rash.

[Recall of Zicam Extreme Congestion Relief Nasal Gel by Matrixx Initiatives](#) (Dec 19)

Burkholderia cepacia was found in a single sample of Zicam Extreme Congestion Relief nasal gel, a nasal decongestant, and could lead to respiratory infections in individuals with a compromised immune system or those with chronic lung conditions.

[Recall of Libigrow, Libigrow XXXtreme, Blue Diamond, Blue Diamond Platinum, Mojo Nights, Mojo Nights Supreme, And Casanova by Performance Plus Marketing, Inc.](#) (Dec 18)

Libigrow, Libigrow XXXtreme, Blue Diamond, Blue Diamond Platinum, Mojo Nights, Mojo Nights Supreme, and Casanova, dietary supplement sexual enhancers for men, contain undeclared Sulfoildenafil and Thioildenafil and may interact with nitrates found in some prescription drugs such as nitroglycerin and may lower blood pressure to dangerous levels.

[Xyrem \(sodium oxybate\) - Warning Against Use With Alcohol or Drugs Causing Respiratory Depression](#) (Dec 17)

Xyrem (sodium oxybate), to reduce attacks of muscle weakness (cataplexy) and daytime sleepiness, combined with alcohol or central nervous system (CNS) depressant drugs can markedly impair consciousness and may lead to severe breathing problems (respiratory depression).

[Recall of Carboplatin Injection by Hospira](#) (Dec 15)

Carboplatin Injection, for treatment of advanced ovarian carcinoma, previously recalled due to visible particulates have been identified as Carboplatin crystals.

[Chantix \(Varenicline\) - Updated Safety Review On The Risk of Cardiovascular Adverse Events](#) (Dec 12)

A higher occurrence of major adverse cardiovascular events were observed in a large, combined analysis of Chantix, a prescription medicine used to help adults quit smoking, compared to placebo but was not statistically significant. It is uncertain whether the excess risk for the Chantix group was due to the drug or due to chance.

[November 2012 Safety Labeling Changes](#) (Dec 11)

The summary view includes drug products with safety labeling changes to the BOXED WARNING, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, ADVERSE REACTIONS, or PATIENT PACKAGE INSERT/MEDICATION GUIDE sections.

[Protandim by LifeVantage Corporation: Recall - Possible Metal Fragments in Product](#) (Dec 7)

Protandim, the Nrf2 Synergizer dietary supplement, were distributed in the United States and Japan between July and November 2012.

[Heparin: Container Labels to Clearly State the Total Drug Strength](#) (Dec 6)

Manufacturers of Heparin Lock Flush Solution, USP and Heparin Sodium Injection, USP will be required to clearly state the strength of the entire container of the medication followed by how much of the medication is in 1 milliliter (mL).

[Nationwide Recall of 101 Lots of Hydrocodone Bitartrate and Acetaminophen Tablets, Up 10 Mg/500 Mg by Qualitest](#) (Dec 6)

It is possible that a number of tablets from the affected lots may exceed the weight requirement and could exceed the label claim potency requirements for the ingredients of hydrocodone bitartrate and acetaminophen.

[Ondansetron \(Zofran\) 32 mg, Single Intravenous \(IV\) Dose Removed Due to Potential For Serious Cardiac Risks](#) (Dec 4)

These drugs are sold pre-mixed in solutions of either dextrose or sodium chloride in plastic containers used to prevent chemotherapy-induced nausea and vomiting. They will no longer be marketed because of the risk of QT interval prolongation, which can lead to Torsades de Pointes, an abnormal, potentially fatal heart rhythm.

[Recall of Atorvastatin Calcium Tablets by Ranbaxy Inc. Due to Foreign Substance](#) (Nov 28)

The product is used to lower blood cholesterol and there are 41 affected lots of tablets (10 mg, 20 mg and 40 mg) packaged in plastic bottles with 90 and 500 tablets.

[Recall of Isovue \(iopamidol injection\) Pre-Filled Power Injector Syringes by Bracco Diagnostics Inc. Due to Particulates](#) (Nov 28)

Isovue is indicated for angiography throughout the cardiovascular system, and arterial injection of Isovue (for cerebral angiography) with particulate matter formation could cause stroke.

For more product safety information, please visit our MedWatch [website](#).

PRODUCT APPROVALS:

[FDA Approves Signifor, a New Orphan Drug for Cushing's Disease](#) (Dec 14)

FDA approved Signifor (pasireotide diaspertate) injection for the treatment of Cushing's disease patients who cannot be helped through surgery.

[FDA Approves Raxibacumab to Treat Inhalational Anthrax](#) (Dec 14)

FDA approved raxibacumab injection to treat inhalational anthrax, a form of the infectious disease caused by breathing in the spores of the bacterium Bacillus anthracis.

[FDA Approves Iclusig to Treat Two Rare Types of Leukemia](#) (Dec 14)

FDA approved Iclusig (ponatinib) to treat adults with chronic myeloid leukemia (CML) and Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL).

[FDA expands Zytiga's use for late-stage prostate cancer](#) (Dec 10)

FDA expanded the approved use of Zytiga (abiraterone acetate) to treat men with late-stage (metastatic) castration-resistant prostate cancer prior to receiving chemotherapy.

[FDA Approves Cometriq To Treat Rare Type Of Thyroid Cancer](#) (Nov 29)

FDA approved Cometriq (cabozantinib) to treat medullary thyroid cancer that has spread to other parts of the body (metastasized).

For information on drug approvals, please visit [Drugs@FDA](#)

ANNOUNCEMENTS:

[FDA Warns Against Improper Advertising, Promotion of Lasers Intended for LASIK Corrective Eye Surgery](#) (Dec 18)

FDA warned five eye care providers to stop the misleading advertising and promotion of refractive lasers used in eye surgery procedures such as LASIK.

[FDA Announces Public-Private Partnership To Develop Regulatory Science That Will Speed Patient Access To New Medical Device Technologies](#) (Nov 3)

The new Medical Device Innovation Consortium (MDIC) is an independent, nonprofit corporation, created by LifeScience Alley (LSA), and will prioritize the regulatory science needs of the medical device community and fund projects.

RESOURCES:

[The Value of Unique Device Identification \(UDI\) Implementation for Healthcare Systems and Providers](#)

Archived audio and presentation materials are available from the November 5, 2012 webinar.

[FDA Basics Webinar: A Brief Overview of REMS](#)

This presentation will discuss REMS and how they are used to help ensure that the benefits of certain medicines continue to outweigh their risks.

[Consumer Updates](#)

Timely and easy-to-read articles covering all FDA activities and regulated products including:

- [Medication Errors Happen to Pets, Too](#)

[FDA Voice](#)

FDA Voice is the official blog from FDA's senior leadership and staff.

[Fighting Antibiotic Resistance](#)

[MedSun Medical Product Safety Network](#)

The Medical Product Safety Network (MedSun) improves FDA's understanding of problems with the use of medical devices so that the FDA, healthcare facilities, clinicians, and manufacturers can better address safety concerns. The MedSun Web page is a newsletter-based website which provides monthly updates about timely medical device issues that may impact

[2012 Health Professional Organizations Annual Conference - Meeting Summary](#)

The summary captures highlights and presentations from the Second Annual Health Professional Organizations Conference on October 4, 2012.

[A New Law Advances Public Health: New Web Page Tracks Progress](#)

CONSUMER UPDATES:

[Helping Consumers Reduce Sodium Intake](#)

Most Americans consume way too much sodium, with salt (sodium chloride) being the most common form.

Please visit Consumer Updates for [more information](#).

CPO Update



U.S. Public Health Service

Pharmacist Professional Advisory Committee

Chief Professional Officer, Pharmacy Update

January 2013

It is with passion and anticipation that we enter 2013! 2012 was a good year for pharmacy - so thanks to all of you for doing all the hard work and giving your leadership all the tools needed to show everyone how we can improve the Nation's health. I hope each of you worked hard to enjoy the Holiday Season and shared some quality downtime with your families, friends and loved ones. Most importantly, I hope that you are able to reflect upon the support we all receive from the special people in our lives. Our perseverance and your leadership will also allow us to excel in 2013!

In 2012, I challenged all of you with a "Call-to-Action" at every event and venue to lead and transform pharmacy. You did a wonderful job and we experienced advancement of the category and profession nationwide. So many examples we can share. At the same time, you served your missions admirably as pharmacists and officers.

I look forward to my last full year as your CPO – a term that will end early in 2014. It has been a wonderful ride; however it is not yet over and we have all of 2013 to continue to make a difference.

Commissioned Corps Headquarters

- **Deployments** The Corps completed its response to Hurricane Sandy. Well over 400 officers were deployed including many pharmacists. The Department, Assistant Secretary for Health, and Surgeon General – as well as the Deputy Surgeon General and yours truly were proud the Corps and category were able to assist in a time of public health need. We thank the Agencies, supervisors and colleagues that helped to allow us to deploy during this crisis. Remember those that supported you during this time.
- In December, the tragedy in Newtown Connecticut also unfolded. The state of Connecticut requested a team of mental health professionals be deployed by the U.S. Department of Health and Human Services (HHS) to Newtown, CT. There were almost 30 USPHS mental health providers from Mental Health Team (MHT) #4 (with augmentation from MHT#3, MHT#5 and Services Access Team (SAT) #3, supporting and providing services and consultation for a total of 8 missions in and around Newtown, CT. Please be aware that your leadership in the Office of the Surgeon General and Commissioned Corps HQ worked in close partnership with the Office of the Assistant Secretary for Health, the Assistant Secretary for Preparedness and Response and other Departmental assets to assure the best outcomes.

- **This is (once again) an expected responsibility of our Corps as an asset to the Department.** This is why we remain basic ready AT ALL TIMES, not just during promotion season. That is a requirement. Basic Readiness is mandated. It is not a promotion-specific requirement. It is an 'active-duty' requirement and policy. Continue to maintain readiness even when you are NOT up for promotion. We will be monitoring this more closely. At this time, policy dictates administrative actions if you are not Basic Ready when up for promotion; however there may be stronger enforcement in the near future if you are not Basic Ready at any point in time (if left unresolved).
- **Human Resources:** HQ continues to experience a major transition (and reduction) in staffing. You may see positions/vacancies being announced. There may be a misperception that we are adding to existing staff; however most of the new hires are simply replacing officers that have left for various reasons. The budget dictates how many FTEs can be carried at HQ; therefore we will likely remain static at this baseline for the foreseeable future.
- **Billets:** The Promotion Information Report (PIR) now reflects the position title and position (billet) grade assigned as a result of the transformation to the Direct Access Billet System (DABS). For most officers, this will be the final change resulting from this effort. While some corrections may still need to be made, it is important at this time that we ensure that the PIR reflects the transformation changes and provide officers, especially officers eligible for competitive promotion during the 2013 promotion year (PY), the opportunity to confirm their position grades. Officers eligible for promotion in PY2013 should immediately review and confirm their position grade in the PIR.
- There is a two-year period following the transformation of an officer's billet, during which any position (billet) experiencing a grade change shall be reported in the officer's PIR as the higher grade of the legacy billet or new position. This two-year period will include the 2013 and 2014 promotion boards. All officers should review the Position/Billet Implementation Grade Personnel Operations Memorandum for more information (http://dcp.psc.gov/eccis/documents/POM12_004.pdf).
- **Should you have questions** about your position information, please first review the Direct Access Billet System Frequently Asked Questions (FAQs) posted on the CCMIS website. These FAQs will be regularly revised. Additional questions may be directed to your Commissioned Corp Liaison or PAC leadership as appropriate.
- **MAB/Compensation:** As you may be aware, all Medical affairs, Compensation, and Commissioned Corps IT support are now integrated into the Office of Surgeon General. This consolidates all Corps functions under Corps leadership and will be a continuous process across the next year. This is a desired end-state; however fiscal resources and full integration are being discussed frequently to ensure seamless transition. ALL contact numbers are updated so all documents will be received for promotion, COERs, etc.
- **Application Processes:** The Corps no longer needs Senate confirmation for any calls-to-active duty. This regulation was passed and signed on August 10, 2012 by President Obama.
 - If candidates are willing to go to the locations of most need, medically underserved and vulnerable populations, including clinical positions within IHS, BOP and Immigration, we will be able to get through the applicant pool more efficiently and look toward new applicants.
 - HQ is planning to open up a new call-to-active duty process in late Spring, early Summer. There will be more information forthcoming. However, this will reflect more targeted recruitment and an increased focus on putting the best candidates in our uniform. There is no shortage of pharmacy students or pharmacists that apply to the Corps. Our goal is to get capture the right type of officer and person to commissioned into the Corps.

- If you have detailed questions, your Commissioned Corps liaisons, Professional Advisory Committee, and DCCPR Assignments Team should be able to provide additional information and answer your questions. It is preferred that you do not email OSG or DCCPR Director as the first line of questioning. I appreciate your consideration of this; however our goal is to be responsive regardless.
- **Corps HQ will continue to post important messaging through internal listserves...Please check all your emails for announcements. It is an officer's responsibility to be current.**

Policy

- Continue prideful uniform wear. We have observed a wonderful and appropriate response to the uniform wear messaging. We have not encountered a single instance (with use of positive messaging) where there was an unresolved issue of uniform wear to this point.

Pharmacy COSTEPs

- We are pleased to say the COSTEP will continue within the Pharmacy Category in 2013. We will work closely with Corps HQ to make sure it is completed more smoothly than the previous two years with renewed support from Office of the Assistant Secretary for Health (OASH). This year will be the first we have streamlined applicant pool to those categories (Pharmacy, Engineers, and EHOs) that utilize the COSTEP program the most. This will reduce overall applications and those that are in these three categories will be processed more efficiently. If you are going to support a COSTEP, please make this known to your pharmacy lead in the Agency.

Pharmacy APFT Initiative

- Proud to relay that this initiative is ongoing and growing day-by-day. You will receive an update from the pharmacy leads of this initiative. This initiative is not only supported by your PAC and CPO, but also DCCPR as our category serves as the pilot category for this initiative. I encourage all of you to participate.

Promotions

- All documents were due at the end of the 2012 calendar year as customary. Please attempt to submit an APFT (instead of President's Challenge) for the fitness requirement - we will continue to move toward APFT-only requirements.

OBC

- Schedule is on CCMIS: <http://dcp.psc.gov/CCMIS/COTA/obcdates.aspx>. Please join us for the OBC Pinning and Graduation ceremonies. It is always good to see pharmacy well represented at the events.

COER

- The 2012 COER should have been completed by Dec 31st.

NEW Deployment Uniforms (ODU)

- To reiterate - the new deployment uniform has been released. Please refer to the personnel policy memorandum at http://dcp.psc.gov/eccis/documents/PPM12_002.pdf. A very helpful "How to Order" guide is also posted here: [http://dcp.psc.gov/ccmis/PDF_docs/Directions%20%20Guidance%20for%20Ordering%20ODU%20online_31Aug12%20\(3\).pdf](http://dcp.psc.gov/ccmis/PDF_docs/Directions%20%20Guidance%20for%20Ordering%20ODU%20online_31Aug12%20(3).pdf).
- All officers will be required to purchase and prepare the ODU by September 1, 2013. The BDU is allowable until September 1, 2013.

Meetings

- APhA Mid-Year in Los Angeles upcoming (first week in March). I will be there for the Friday Federal Pharmacy Forum. Hope to see you there.

CPO Initiatives Update

- Invitations to speak about the Report to the Surgeon General frequently continue. Thanks to all those who have functioned as surrogates for me and presented the Report at large venues, including RADM Chris Bina, CAPT Ed Stein, CDR Sherri Yoder, CDR Mike Lee, CDR Greg Davis and CDR Ryan Schupbach. Keep up the great work.
- Article published in the APhA *Pharmacy Today* December Issue.
- *U.S. Medicine 2013 Outlook* should be published in January 2013.
- Currently PHS Pharmacy has representative pharmacists involved in multiple government pharmacy-related initiatives, including Million Hearts, Interagency Committee on ADEs, Adherence Call-to-Action, and review of multiple white papers with external organization partners. Great job.
- As always, please consider utilizing the PharmPAC leadership (CDR Mike Crockett or LCDR Marisol Martinez) and LCDR Eunice Chung-Davies (eunice.chung-davies@fda.hhs.gov) for any CPO business related issues.

Summary of Actionable Items (This is why you joined the Corps...to do more):

1. Review thoroughly this CPO Update. It contains more than the usual amount of information and updates.
2. Purchase/Prepare your new ODU for deployment.
3. Complete the APFT (only 25% of pharmacists are left to switch from President's Challenge to the APFT! – Great job).
4. Report out on any direct or indirect impact from the *Pharmacy Report to the Surgeon General* to RADM Giberson and/or LCDR Eunice Chung-Davies.

Thank you for all your hard work and efforts! You are transforming our category and the profession!

RADM Giberson